K020274

WRIGHT
MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
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FEB 2 2 2002

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the **WMT MODULAR ULNAR HEAD**.

Submitted By:	Wright Medical Technology, Inc.
Date:	January 25, 2002
Contact Person:	Ehab M. Esmail Manager, Regulatory Affairs
Proprietary Name:	WMT MODULAR ULNAR HEAD
Common Name:	ULNAR HEAD IMPLANT
Classification Name and Reference:	21 CFR 888.3810 Prosthesis, WRIST, HEMI-, ULNAR – Class II
Device Product Code and Panel Code:	Orthopedics/87/ KXE

DEVICE INFORMATION

A. INTENDED USE

The WMT Modular Ulnar Head Implant is indicated for the following indications :

- Replacement of the distal ulnar head for disorders of the distal radioulnar joint in rheumatoid, degenerative and post-traumatic arthritis presenting with the following findings:
  -pain and weakness of the wrist joint not improved by nonoperative treatment;
  -instability of the ulnar head with radiographic evidence of dislocation or erosive changes of the distal radioulnar joint;
  -failed ulnar head resection; e.g. Darrach resection
- Primary replacement after fracture of the ulnar head or neck.
- Revision following failed ulnar head arthroplasty.

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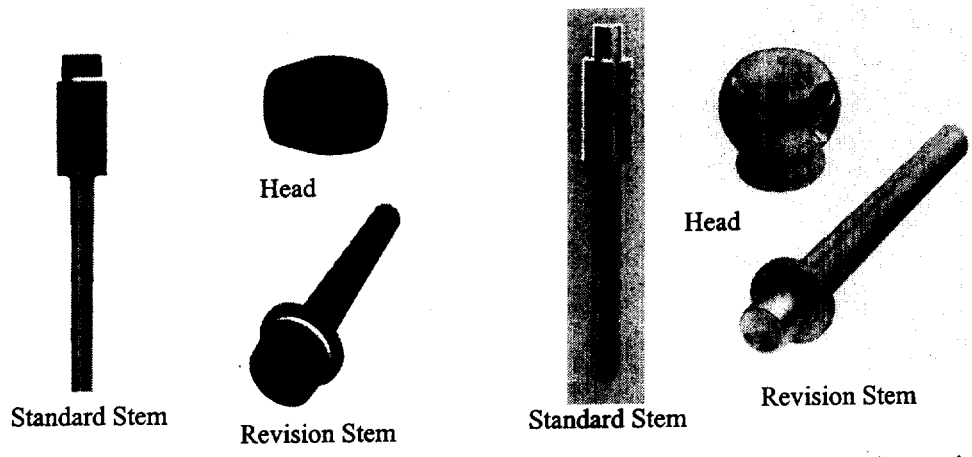
B. DEVICE DESCRIPTION

The design features of the WMT Modular Ulnar Head Implant (Figure 1) is substantially equivalent to the Avanta uHead™ modular ulnar head implant (previously submitted and cleared under AVANTA ULNAR HEAD IMPLANT – 510(k): K010786).

Figure 1 - Comparison Between WMT and Avanta uHead™ modular ulnar head implants



The WMT Modular Ulnar Head Implant was designed as a more anatomic alternative to the previously submitted and cleared Avanta uHead™ modular ulnar head implant (previously submitted and cleared under AVANTA ULNAR HEAD IMPLANT – 510(k): K010786) that utilizes axisymmetric head and stem components. The anatomy of the distal ulna is not axisymmetric, but rather consists of a head that is offset medial-lateral and dorsal-volar from the ulnar canal. Cadaveric analysis has shown that there is no correlation between head and stem location, thus a system where the head is offset relative to the stem is required to replicate normal anatomy and thus, joint kinematics.

The WMT Modular Ulnar Head is manufactured from cobalt chrome (ASTM F799 or F1537). The triangulated head will have a highly polished exterior surface across the articulating arc and distal surface, and will have a plasma sprayed textured surface laterally for tissue adhesion. The heads will be available in sizes ranging from 16mm to 22mm in diameter, 8mm to 11mm in height, and 1.5mm to 3mm in offset. The WMT Modular Ulnar Head Implant will contain suture holes for attaching soft tissues and a locking taper mechanism for engaging the modular head onto the stem.

The WMT Modular Ulnar Stem is manufactured from titanium (ASTM F136). The stems will be available in a standard and revision option: the standard stem will be tapered 4.5° to match the anatomical canal geometry while the revision stem will have a 1° taper to match proximal canal geometry. Each stem option will be available in distal diameters ranging from 5.5mm to 8mm and in two lengths: a standard length will have a 1mm platform and 25mm stem, and the extended length will have a 20mm platform and a

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50mm stem. The stems will be fluted and will have a heavy grit blast finish over entire part except for the taper.

Table 1 is a comparison chart summarizing the above design features for the WMT modular ulnar head implant, the Avanta uHead™ modular ulnar head implant and DCW/WMT Swanson silicone ulnar head implant.

Table 1 - Comparison between WMT modular ulnar head implant, the Avanta uHead™ modular ulnar head implant and DCW/WMT Swanson silicone ulnar head implant

Attribute	WMT modular ulnar head implant	Avanta uHead™ modular ulnar head implant	DCW/WMT Swanson silicone ulnar head implant
Sizes	8 heads, 6 stems	3 stems, 3 heads	7
Modularity	Yes	Yes	No
Locking Mechanism	Taper	Taper	N/A
Material (head/stem)	Head: CoCr (ASTM F1537 or F799) with plasma spray Stem: titanium alloy (ASTM F136)	Head: CoCr (ASTM F1537, F75 or F799) Stem: CpTi (F67)	Silicone
Suture Attachments	Yes	Yes	Yes
Bone Fixation	Cement or Uncemented	Cement or Uncemented	
Indications	Same	Same	Same

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, material, type of interface, and design features of the WMT Modular Ulnar Head Implant are substantially equivalent to the Avanta uHead™ modular ulnar head implant (previously submitted and cleared under AVANTA ULNAR HEAD IMPLANT – 510(k): K010786). The safety and effectiveness of the WMT Modular Ulnar Head Implant are adequately supported by the substantial equivalence information, materials data, and testing results provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2 2002

Mr. Ehab M. Esmail
Manager, Regulatory Affairs
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K020274
Trade Name: WMT Modular Ulnar Head Implant
Regulatory Number: 888.3810
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories; and smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: KXE
Dated: January 25, 2002
Received: January 28, 2002

Dear Mr. Esmail:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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WMT Modular Ulnar Head Implant

INDICATIONS STATEMENT

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  -pain and weakness of the wrist joint not improved by nonoperative treatment;
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  -failed ulnar head resection; e.g. Darrach resection
- Primary replacement after fracture of the ulnar head or neck.
- Revision following failed ulnar head arthroplasty.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number _____

Prescription Use X
(Per21 CFR 801.109)

OR

Over-The Counter Use ____
(Optional Format 1-2-96)

for Mark N. Melkerson
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020274

WRIGHT MEDICAL TECHNOLOGY
A Wright Medical Group Company